Clinical interventions in COPD

P137 EFFICACY AND SAFETY OF ONCE-DAILY ACLIDINIUM BROMIDE 200 μg IN COMBINATION WITH FORMOTEROL IN PATIENTS WITH COPD

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Methods Patients with chronic respiratory disease undertook a HCT by the ROBD and Ventimask methods. The FiO2 was 15.1% to simulate 8,000 ft which is equivalent to the maximum cabin altitude patients are likely to encounter during commercial air travel.

Results 60 patients, (45 males) with stable chronic obstructive or restrictive respiratory disease participated in the study; age mean (SD) 57 (15) years, FEV1 66 (27)% FVC 66 (27)% FEV1/FVC ratio 60 (18). There was no significant difference between PaO2 pre-ROBD HCT 9.74 (1.19) and pre-Ventimask HCT 9.72 (1.05) paired t-test p=0.05. PaO2 measured post-ROBD HCT (7.36 (0.93)) was significantly lower compared to PaO2 post-Ventimask HCT (7.96 (0.97)) (p=0.01). There was no significant difference in the mean decrease in SpO2 in-flight mean (SD) 6 (3) compared to the mean decrease in SpO2 post-ROBD HCT 5 (3) (p=0.334). In contrast, there was a significant difference in the mean decrease in SpO2 post-Ventimask HCT 3 (2) compared to the mean decrease in SpO2 in-flight and post-ROBD HCT (p=0.01)

Conclusion The ROBD HCT results in a lower PaO2 compared to a Ventimask HCT at a FiO2 of 15.1%. The ROBD assessment more accurately reflected actual changes in SpO2 in-flight and may be a better method of assessment for in-flight oxygen.

P138 EFFICACY OF INHALED PAN-SELECTIN ANTAGONIST BIMOSIAMOSE ON OZONE-INDUCED AIRWAY INFLAMMATION IN HEALTHY SUBJECTS

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Introduction Combinations of different classes of medication used in the management of chronic obstructive pulmonary disease (COPD) may provide additional improvements compared with monotherapy. This study assessed the efficacy and safety of aclidinium bromide 200 μg, a novel long-acting muscarinic antagonist, combined with formoterol, a long-acting β-agonist. All combination and mono-therapy treatments were delivered as single inhalations.

Methods 566 patients with moderate to severe COPD were randomised in a double-blind manner to receive aclidinium plus formoterol 6 μg (n=121), 12 μg (n=120) or 18 μg (n=125), or monotherapy with aclidinium (n=76), formoterol 12 μg (n=65) or placebo (n=59). Treatment was administered once-daily for 4 weeks via the Genuair® inhaler, a multidose dry powder inhaler. The primary efficacy endpoint was change from baseline in normalised forced expiratory volume in 1 second (FEV1) area under the curve over 12 h (AUC0–12h) at 4 weeks. Safety was assessed throughout the study.

Results There was a mean (±SE) increase from baseline in normalised FEV1 AUC0–12h at 4 weeks with aclidinium plus formoterol 6 μg (n=121), 12 μg (n=120) or 18 μg (n=125), or monotherapy with aclidinium (n=76), formoterol 12 μg (n=65) or placebo (n=59). Treatment was administered once-daily for 4 weeks via the Genuair® inhaler, a multidose dry powder inhaler. The primary efficacy endpoint was change from baseline in normalised forced expiratory volume in 1 second (FEV1) area under the curve over 12 h (AUC0–12h) at 4 weeks. Safety was assessed throughout the study.

Conclusions Aclidinium combined with formoterol provided greater improvements in pulmonary parameters than either drug alone or placebo. The bronchodilation provided by aclidinium and formoterol 18 μg was comparable to aclidinium and formoterol 12 μg, suggesting the optimal dose of formoterol was 12 μg. No safety concerns arose during the study. These findings support the combination of aclidinium and formoterol for the treatment of COPD.